

REMARKS

Claims 1-8 and 10-12 were pending in the present application. Claims 7, 8 and 10-12 have been amended herein and new claim 13 has been added. Support for the amended claims and new claim can be found throughout the specification and original claims. No new matter has been added. Upon entry of the present amendment, claims 1-8 and 10-13 will be pending.

As a preliminary matter, Applicants note that the citations of PCT/GB02/05743 on pages 1, 2, and 4 of the present application are the result of a clerical error. PCT/GB02/05738, and not PCT/GB02/05743, corresponds to WO 03/051821 which corresponds to U.S. 2005/0171204 (Linstedt et al.). The specification has been amended herein, to correct the clerical error.

I. The Claimed Invention Is Not Obvious

Claims 1-12 have been rejected under 35 U.S.C. §103(a) as allegedly being obvious over Linstedt et al. (US 2005/0171204), which is alleged by the Office to broadly teach salts of compound of formula I and specifically mention alkaline earth metal salts, because the instant invention claims particular alkaline earth metal salts, magnesium and calcium, of the compound of formula I. *See* Office Action at page 6. Applicants traverse the rejection and respectfully request reconsideration thereof, because the Examiner has not established a *prima facie* case of obviousness.

A *prima facie* case of obviousness requires that the teachings of the prior art suggest the claimed compounds to a person of ordinary skill in the art (emphasis added). *See In re Deuel*, 51 F.3d 1552, 1557, 34 U.S.P.Q.2d 1210, 1214 (Fed Cir. 1995). The mere fact that a prior art genus contains a small number of members does not create a *per se* rule of obviousness. Some motivation to select the claimed species or subgenus must be taught by the prior art. *See Id.* at 1558-1559. Linstedt et al. report a broad genus of compounds which includes pharmaceutically acceptable salts of a compound of formula I; and more specifically, alkaline earth metal salts. However, specific pharmaceutically acceptable salts of the compounds of the formula I are not taught by Linstedt et al. Moreover, Linstedt et al. do not teach or suggest calcium or magnesium salt forms of the compound of formula I or methods of preparation thereof. In fact, Linstedt et al. do not teach methods of preparation for any crystalline forms of the compound of formula I. Thus, a person skilled in the art, armed with the disclosure of Linstedt et al., would not be

motivated to select calcium or magnesium from the litany of pharmaceutically acceptable salts reported therein. Accordingly, the Examiner has not established a *prima facie* case of obviousness. Failing to do so, the burden has not properly shifted to Applicants.

In light of the foregoing discussion, Applicants respectfully assert that Claims 1-8, and 10-12 are not obvious, and request the claim rejection be withdrawn.

II. The Claimed Invention Is Enabled

Claims 8 and 9 have been rejected under 35 U.S.C. §112, first paragraph as allegedly failing to enable the claimed invention. Applicants note that claim 9 was canceled in a Preliminary Amendment filed December 9, 2005. It is Applicants belief that the Action intended to reject the subject matter of claim 10 and not claim 9. The comments that follow are directed accordingly.

The Office alleges that while being enabling for methods of treatment of dyslipidemia and type 2 diabetes, the specification does not reasonably provide enablement for prevention of dyslipidemia and type 2 diabetes. The Office bases its allegation on the premise that the art does not recognize preventive therapeutic agents for dyslipidemia or type 2 diabetes. *See* Office Action at page 3. Applicants traverse the rejection and respectfully request reconsideration thereof, because a person skilled in the art would be able to make and use the claimed invention without being required to perform undue experimentation.

As a preliminary matter, Applicants thank Examiner for pointing out that the present application is enabled for “treating dislipidemia and type 2 diabetes.” Although Applicants assert that “preventing lipid disorders (dyslipidemias)” is also enabled, in order to expedite prosecution and without disclaimer of subject matter, claim 8 has been amended accordingly. In addition, Applicants respectfully assert that “preventing type 2 diabetes” is also enabled and attach hereto a Position Statement (“Statement”) released by the American Diabetes Association and the National Institute of Diabetes, Digestive and Kidney Diseases, in support of this assertion.

The Statement teaches that there is now substantial evidence that type 2 diabetes can be prevented (see Statement, Diabetes Care, 25(4): 742-749 (2002)). The Statement also teaches that knowledge of the early stages of hyperglycemia that portend the diagnosis of diabetes, and the recent success of major intervention trials, clearly show that individuals at high risk can be identified and diabetes delayed, if not prevented (see Statement, at 743-744). This suggests that

type 2 diabetes can be prevented, and that one skilled in the art could reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to “prevent type 2 diabetes” as claimed by Applicants. The Statement further teaches that three diabetes prevention trials used pharmacological therapy, and all reported a significant lowering of the incidence of diabetes. (see Statement 1, at 745). According to Merriam Webster On-Line Dictionary, “prevent” means to “keep from happening.” Merriam Webster On-Line Dictionary <http://www.m-w.com/dictionary/prevent> (June 27, 2007). According to Dorland’s Medical Dictionary, “incidence” is derived from the root “incidere,” which means “to happen.” Thus, Applicants respectfully assert that “preventing type 2 diabetes” is also enabled.

In view of the foregoing discussion, Applicants respectfully assert that claims 8 and 10 meet the requirements of 35 U.S.C. §112, first paragraph, and request the claim rejection be withdrawn.

III. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicants’ undersigned representative at (610) 640-7859 if there are any questions regarding Applicants’ claimed invention.

The Commissioner is hereby authorized to debit any underpayment of fee due or credit any overpayment to deposit account 50-0436.

Respectfully submitted,

/Paul K. Legaard, Reg.# 38534/

Paul K. Legaard

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Pepper Hamilton LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312-1183

Telephone: 610.640.7859
Facsimile: 267.430.7647